The opinion in support of the decision being entered today was <u>not</u> written for publication and is <u>not</u> binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte C. ALEXANDER TURNER, JR., GREGORY DONOHO, XIAOMING WANG, ERIN HILBUN, BRIAN ZAMBROWICZ, and ARTHUR T. SANDS

> Appeal No. 2005-2379 Application No. 09/689,911

MAILED

SEP 2 3 2005

U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

ORDER UNDER 37 CFR § 41.50(d)

Before WILLIAM F. SMITH, ADAMS and GRIMES, <u>Administrative Patent Judges</u>. GRIMES, <u>Administrative Patent Judge</u>.

ORDER UNDER 37 CFR § 41.50(d)

Under the provisions of 37 CFR § 41.50(d),¹ we require Appellants to address the following matters:

We invite attention to commonly assigned Application No. 09/714,882.² That application was the subject of an appeal to this board (Appeal No. 2004-1732), which was decided on September 24, 2004.

¹ "The Board may order appellant to additionally brief any matter that the Board considers to be of assistance in reaching a reasoned decision on the pending appeal. Appellant will be given a non-extendable time period within which to respond to such an order." 37 CFR § 41.50(d).

² The named inventors in the instant application are C. Alexander Turner, Jr., Gregory Donoho, Xiaoming Wang, Erin Hilbun, Brian Zambrowicz, and Arthur T. Sands. In Application No. 09/714,882, the inventors are C. Alexander Turner Jr., Michael C. Nehls, Glenn Friedrich, Brian Zambrowicz, and Arthur T. Sands.

The issues and arguments in Appeal No. 2004-1732 bear close resemblance to those in this appeal. In Appeal No. 2004-1732, the broadest independent claim (claim 2) was directed to "[a]n isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO:2." The polypeptide of SEQ ID NO:2 was disclosed to have sequence similarity to Notch receptor ligands, but the specification did not disclose the biological function of the putative ligand. The only issue in Appeal No. 2004-1732 was whether the specification disclosed a patentable utility for the claimed invention.

In Appeal No. 2004-1732, the appellants argued, among other things, that the claimed nucleic acids had utility because they could be used in methods that do not depend on the biological activity of the encoded protein. The appellants argued that the claimed nucleic acids were useful "in determining the genomic structure of the corresponding human chromosome . . ., for example mapping the protein encoding regions" and that they "are useful for functionally defining exon splice-junctions."

Application No. 09/714,882, Board decision mailed 9/24/04, page 18.

The appellants in Appeal No. 2004-1732 also argued that the claimed nucleic acids could be used in "gene chips" or "DNA chips" to monitor gene expression. The appellants argued that "[s]uch "DNA chips" clearly have utility, as evidenced by hundreds of issued U.S. Patents. . . . Clearly, compositions that <u>enhance</u> the utility of such DNA gene chips, such as the presently claimed sequences encoding a testis specific <u>Notch</u> ligand, must in themselves be useful." <u>Id.</u>

The panel that decided Appeal No. 2004-1732 reviewed governing principles of law; addressed and rejected the appellants' arguments premised on DNA chips, gene

mapping, and exon splice junctions; and concluded that "Appellants' disclosure in th[at] case does not provide a specific benefit in currently available form, and therefore lacks the substantial utility required by 35 U.S.C. § 101." <u>Id.</u>, page 27. Accordingly, the examiner's decision, rejecting all of the pending claims in Application No. 09/714,882, was affirmed.

As in Application No. 09/714,882, the broadest claim in this appeal (claim 3) is directed to "[a]n isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO:2." In this case, the claimed nucleic acid is disclosed to encode a protein that "share[s] structural similarity with animal galanins." Specification, page 1. The specification also states that "[t]he first 14 residues of mature galanin proteins are highly conserved. Unlike other known galanins, the presently described sequences differ at amino acid 14 of the consensus sequence shared by other galanins." Pages 1-2. The specification does not disclose any biological activity of the polypeptide of SEQ ID NO:2, or any other basis for using the protein or DNA encoding it in a practical way. All of the claims stand rejected for lack of patentable utility. Examiner's Answer, page 3.

The Appeal Brief in this appeal includes essentially the same arguments that were made and rejected by the previous merits panel in Appeal No. 2004-1732.³ For example, Appellants argue that:

³ In addition to the arguments quoted above, Appellants cite a paper published in December 1999 as describing and characterizing a protein that "shares 100% identity at the amino acid level with the first 98 amino acids" with SEQ ID NO:2. The instant application, however, has an effective filing date of October 1999 and Appellants have not shown that the later-published paper reflects the state of the art as of the filing date. In addition, Appellants argue that they have made knock-out mice that show that the protein encoded by the claimed polynucleotides is involved in inflammation. Appellants, however, have pointed to no evidence in the record to support these arguments – attorney argument is not evidence. Appellants' argument based on knock-out mice is unsupported by evidence in the record and therefore unpersuasive.

Application No. 09/689,911

- "Clearly, the present polynucleotide provides exquisite specificity in localizing the specific region of human chromosome 19 that contains the gene encoding [sic, comprising?] the given polynucleotide. . . . The presently claimed polynucleotide sequence defines a biologically validated sequence that provides a unique and specific resource for mapping the genome." (Appeal Brief, page 12);
- "The presently claimed polynucleotide sequence provides <u>biologically validated</u> empirical data (e.g., showing which sequences are transcribed, spliced, and polyadenylated) that <u>specifically</u> define that portion of the corresponding genomic locus that actually encodes exon sequence." (<u>id.</u>);
- "[G]iven the obvious medical relevance of the presently claimed sequences, those of skill in the art would readily appreciate the importance of tracking the expression of genes encoding the described proteins. . . . Such 'DNA chips' clearly have utility, as evidenced by hundreds of issued U.S. Patents. . . . Clearly, compositions that <u>enhance</u> the utility of such DNA chips, such as the presently claimed nucleotide sequences, must in themselves be useful." (<u>id.</u>, page 8);

On these facts, we require Appellants to explain why we should again address the same line of argument in this case: since the same arguments were considered and thoroughly addressed in Appeal No. 2004-1732, why would the previous panel's treatment of those arguments not be dispositive here? In particular, why should the facts and arguments set forth in the briefing of this appeal lead to a different conclusion than that reached by the panel in Appeal No. 2004-1732, which rejected the same arguments? We note that, according to PTO records, the appellants in Appeal No. 2004-1732 (Application No. 09/714,882) did not request rehearing under 37 CFR § 41.52, nor did they appeal the Board's decision, within two months from the date of the Board decision; the application has been abandoned.

Conclusion

In conclusion, we require Appellants to address the foregoing matters "consider[ed] to be of assistance in reaching a reasoned decision on the pending appeal." 37 CFR § 41.50(d). We caution, however, that this is not an invitation to

expand on points raised in the Appellants' brief or to rehash arguments already set forth in the brief. This is not an invitation to raise arguments or issues on appeal, or to collaterally attack the decision in Appeal No. 2004-1732. See 37 CFR § 41.37(c)(1)(vii) ("Any arguments or authorities not included in the brief or a reply brief filed pursuant to § 41.41 will be refused consideration by the Board, unless good cause is shown"). Appellants' response should be confined to the matters outlined above.

Time Period For Response

A period of one month from the date of this order is set for Appellants' response.

This time is non-extendable.

Failure to respond in a timely manner will result in dismissal of the appeal.

37 CFR § 41.50(d)

William F. Smith

Administrative Patent Judge

Donald E. Adams

Administrative Patent Judge

BOARD OF PATENT

APPEALS AND

) INTERFERENCES

Eric Grimes

Administrative Patent Judge

EG/jlb

Leexicon Genetics Incorporated 8800 Technology Forest Place The Woodlands, TX 77381